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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,237	04/20/1999	EIICHIRO YAGI	TOS-123-USA	1426

7590

12/10/2001

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 12/10/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.	Applicant(s)	
09/147,237	YAGI ET AL.	
Examiner	Art Unit	
Francisco C Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 5-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 15-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

The request filed on October 23, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/147,237 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 1-17 are presented for examination.

***Election/Restriction***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, and 15-17 drawn to glutathione-containing therapeutic compositions.

Group II, claim(s) 5 and 6, drawn to Scutellaria root extract-containing therapeutic compositions.

Group III, claim(s) 7 and 8, drawn to linden extract-containing therapeutic compositions.

Group IV, claim(s) 9 and 10, drawn to clove extract-containing compositions.

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Group V, claim(s) 11 and 12, drawn to Geranium herb extract-containing compositions.

Group VI, claim(s) 13 and 14, drawn to rosemary extract-containing compositions.

The inventions listed as Groups I through VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Each of the groups recites a different product having different ingredients. Thus, a reference anticipating one of the groups would not necessarily anticipate or even render obvious any of the other groups. In such a situation a general inventive concept clearly is not present.

Applicant's election of the group I invention, claims 1-4, in Paper No. 6, filed June 25, 1999, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 5-14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. As discussed immediately above, election was made without traverse in Paper No. 6, filed June 25, 1999.

Claims 1-4 and 15-17 are examined on the merits.

***Claim Rejections - 35 USC § 102***

Claims 1-4 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by N'Guyen et al (U.S. Pat. 5,023,235).

N'Guyen '235 discloses the preparation of a "Solar cream" which comprises 0.05 weight percent glutathione. See col. 7, lines 12-35, especially line 22. Inherent in the disclosure of a product as a "solar cream" is the disclosure of applying said cream to the skin before or during exposure to ultraviolet light. Thus, the reference discloses applying a composition having the claimed active ingredient in the claimed amount to the claimed part of the body of the claimed recipient. The reference therefore discloses all of the process steps claimed.

It is noted that the claims now recite the administered composition as one having an active ingredient "consisting essentially of" glutathione. It is also noted that the composition disclosed in the '235 patent contains numerous

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ingredients in addition to the glutathione and cosmetic carrier recited in applicant's claims. However, MPEP § 2111.03 clearly states that "[t]he transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention." (Citations omitted, emphasis in original.) On the current record there is no evidence that any of the additional ingredients present in the prior art composition would affect the basic and novel properties of the prior art composition such that the prior art composition is truly different than the claimed composition. Thus, applicant's claims must be construed as encompassing the additional ingredients in the prior art composition, despite the "consisting essentially of" language. A holding of anticipation is therefore required.

Note further that MPEP 2111.03 further provides that "[w]hen an applicant contends that additional steps or materials in the prior art are excluded by the recitation of 'consisting essentially of,' applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention." (Citations omitted.)

All of applicant's argument presented to date regarding this ground of rejection has been fully re-reviewed but is not persuasive of error. It is again noted that the reference refers to a "complexing agent-thiol couple". It is also noted that coupling reactions are known in the art. It is further noted that if the glutathione becomes covalently coupled to the EDTA complexing agent in N'Guyen's compositions, it would then appear that N'Guyen's compositions are not encompassed by the "consisting essentially of" language currently appearing in applicant's claims.

However, as pointed out in the previous office action, there is nothing in the reference indicating that the glutathione and the EDTA complexing agent were subjected to conditions such that the two agents would be "coupled" through covalent bonding, or through electrostatic interaction, or any other type of binding, as alleged by applicant. Because no factual evidence has been provided to demonstrate that the glutathione and EDTA in N'Guyen's become coupled, covalently or otherwise, it is respectfully submitted that the rejection of record is properly maintained.

No claims are allowed.

This is a Continued Prosecution Application of applicant's earlier Application No. 09/147,237. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.




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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP  
December 6, 2001